

Remarks/Arguments

This amendment is responsive to the Office Action of February 17th 2006. Reconsideration of claims 88 - 119 and the new claims 120 – 125 are respectfully requested.

Status of Claims After Amendment

Claims 1 - 87 are canceled in the application.

Claims 93, 98, 111 – 114, 117 are pending in the application.

Claims 88 – 92, 94 – 97, 99 – 110, 115 – 116, and 118 – 119 have been amended in the application.

Claims 120 – 125 are new and appended in the application.

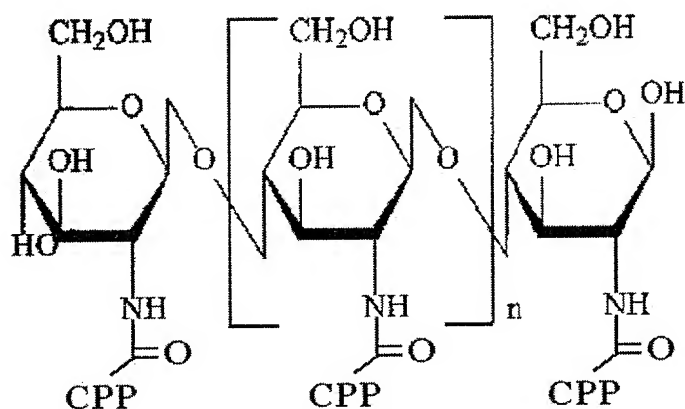
Summary of Amendments

Pursuant to a Telephonic Interview between the Applicant, Michael Gurin and Examiner Anthony on April 27, 2006, in order to clarify the distinction between cited prior art and record of claims in the pending application. All of the independent claims, claims 88, 105, and 118, are now modified to reflect the composition as being a polycationic casein complex. The inclusion of the reference to the casein phosphopeptide being limited within a polycationic complex rather than simply a casein phosphopeptide is the distinction between a composition that respectively actually promotes oxidation as compared to the complex that reduces oxidation.

The currently amended independent claims contain the reference to polycationic that was contained within the original claims 46 and 47 submitted. The currently amended independent claims now further contains the reference to vegetable and animal oils, specifically oils rich in Omega-3 that was contained within the original claim 43, and previously presented claims 60 and 65.

Polycationic is referenced in the original specification in paragraph 54. Chitosan, a claimed polycationic component, is referenced in paragraphs 15, 17, 24, 25, 55 and 95.

A structural representation of the casein phosphopeptide - chitosan complex is shown below for the interaction between caprine caseinophosphopeptides (CPP) and chitosan at pH 6.0., as requested.



The Office Action

Claims 88-119 are pending in this application. The Examiner has rejected claims 99-117 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 88-90, 93-94, 98-103, 105, 107, 111, 113, 115-116 and 118-119 have been rejected under 35 USC §102(b) as being anticipated by Han et al. Claims 95, 104, 106, 108, 114 and 117 have been rejected under 35 USC §103(a) as being unpatentable over Han et al, optionally in view of Antrim et al for claim 114. Claims 91-92, 96-97, 109-110 and 112 are rejected under 35 USC § 103(a) as being unpatentable over Han et al optionally in view of Buikstra et al or Musher et al. Claims 88-119 have been rejected under 35 USC § 103(a) as being unpatentable over Buikstra et al or Antrim et al in view of Han et al.

35 U.S.C. § 112

Claims 99 - 117 were rejected due to being indefinite for failing to particularly point and distinctly claim the subject matter.

Claims 99 - 104 and 106 - 108 were rejected due to improper preamble. All claims have been corrected to have the proper preamble of “The composition according to claim ..”.

Claim 105 was rejected due to being indefinite because of improper use of “and combinations thereof”. Claim 105 has been corrected to have the proper use of “or combinations thereof”.

Claims 109 - 177 were rejected because of their dependence on the rejected claim 105. Claim 105 has been corrected to have the proper use of “or combinations thereof”.

The applicant has carefully amended the claims to address each of the points raised by the Examiner. It is submitted that all claims now comply fully with the requirements of 35 U.S.C. § 112. Applicant considers that the claims are supported by the application as originally filed and are novel as compared to references of record.

35 U.S.C. § 102 (b) and 35 U.S.C. § 103 (a)

Claims 88 - 90, 93 - 94, 98 - 103, 105, 107, 111, 113, 115 - 116 and 118 - 119 stand rejected under 35 U.S.C. § 102 (b) as being anticipated by HAN et al. U.S. Patent Number 5,834,427.

Claims 95, 104, 106, 108, 114 and 117 stand rejected under 35 U.S.C. § 103 (a) as being anticipated by HAN et al. U.S. Patent Number 5,834,427 in view of ANTRIM et al. U.S. Patent Number 4,963,385.

Claims 91 - 92, 96 - 97, 109 - 110 and 112 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over HAN et al. U.S. Patent Number 5,834,427 in view of

BUIKSTA et al. U.S. Patent Number 5,650,190 or MUSHER et al. U.S. Patent Number 2,282,815.

Claims 88 - 119 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over BUIKSTA et al. U.S. Patent Number 5,650,190 or ANTRIM et al. U.S. Patent Number 4,963,385 in view of HAN et al. U.S. Patent Number 5,834,427.

Background of the Law

In order to establish proper anticipation under 35 U.S.C. §102, each and every element of the claimed invention must be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). The claimed elements either be inherent or disclosed expressly in the single prior art reference *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988) and must be arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). The absence from the reference of any claimed element necessarily negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 220 USPQ 81 (Fed. Cir. 1986).

The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; and there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, *or*, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim". *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989).

Obviousness under 35 U.S.C. §103 is a question of law based on findings of underlying *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q (BNA) 459, 467, 15

L.Ed. 2d 545, 86 S.Ct. 684 (1966). To establish a prima facie case of obviousness, there must be some teaching, suggestion, or motivation in the prior art to make the specific combination or modification suggested by the Examiner. *In re Raynes*, 7 F.3d 1037, 1039, 28 USPQ2d 1630, 1631 (Fed. Cir. 1993). Obviousness cannot be established by hindsight combination or modification to produce the claimed invention. *In re Gorman*, 933 F.2d 982, 986, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991).

The Art Cited of Record Fail to Anticipate or Render Obvious the Claimed Invention

In none of the primary references cited by the Examiner is there taught, expressly or by implication, an antioxidant composition including a polycationic casein phosphopeptide. It is submitted that the Examiner has improperly discounted or disregarded the language in the claim preamble that the present invention is an antioxidant composition.

Antrim et al. U.S. Patent Number 4,963,385; BUIKSTA et al. U.S. Patent Number 5,650,190; and HAN et al. U.S. Patent Number 5,834,427 are not directed to a polycationic casein phosphopeptide, but rather simply a casein phosphopeptide, which is the distinction between a composition that respectively actually promotes oxidation as compared to the complex that reduces oxidation.

Han et al. U.S. Patent Number 5,834,427 is directed to a purified casein phosphopeptide “CPP” for enhancing mineral solubility. In such a composition, there is no suggestion of using CPP with unsaturated oils such as Omega-3 rich oils, using CPP as a modified complex, using CPP as a polycationic complex, using a casein source high in alpha-s2, or sourcing the casein from goats (i.e., caprine). The Examiner acknowledges that in Han et al. “there does not seem to be explicit disclosures to applicant’s claimed caprine casein phosphopeptide... of adding pH modifiers... “artificial” fruit concentrate sweetener...” (see Office Action dated February 17, 2006, page 4, para 6) and “there is no explicit disclosure that the compositions to which casein phosphopeptides maybe added to may comprise medium-chain triglycerides and/or phospholipids.” (See Office Action dated February 17, 2006, page 6, paragraph 7.) In addition, there is no disclosure

of tocopherols in Han et al. Accordingly, the rejection of claim 88 and all the dependent claims 89-90, 93-94, 98-103, 105, 107, 111, 113, 115-116 and 118-119 under 35 USC §102(b) as being anticipated by Han et al., should be withdrawn. In response to the rejection of 95, 104, 106, 108, 114 and 117 under 35 USC §103(a) as being unpatentable over Han et al, optionally in view of Antrim et al for claim 114, the Applicant respectfully submit that the cited references do not suggest or provide any motivation to modify or combine the references in the manner suggested by the Examiner. Moreover, one of ordinary skill in the art would not be motivated to make such combination because Han, et al. and Antrim, et al are each directed to different combinations for different intended uses and function.

Antrim et al. U.S. Patent Number 4,963,385 is directed to a oxidative stabilized emulsion for highly unsaturated oils which is comprised of sugars and/or sugar alcohols and a metal-ion chelator. In such a composition, there is no distinction between reducing and non-reducing sugars. There is no suggestion of using non-reducing sugars preferentially over reducing sugars. Any distinction between reducing and non-reducing sugars clearly would have been noted, as fruit concentrate sweetener comprised largely of fructose is a known reducing sugar. The “artificial” fruit concentrate sweetener of the present invention, requires the specification within the dependent claim for the “artificial” fruit concentrate sweetener in order to not become pro-oxidant. Furthermore, there is no distinction between natural and synthetic metal-ion chelators. There is no suggestion that any metal-ion chelator or that multiple metal-ion chelators achieve superior results. Addition of metal-ion chelators without the presence of commercial antioxidants cannot lengthen shelf-life of unsaturated oils, in particular highly unsaturated oils.

Buikstra et al. U.S. Patent Number 5,650,190 is directed to an emulsifying agent that stabilizes the emulsion subjected to heat. In such a composition, the objective is to prevent emulsions that destabilize spontaneously (separation of oil and water phases). There is no mention or implication that stability incorporates oxidative stability as further attributed to the complete absence of terms oxidation, antioxidant, or free radical, and any known antioxidants. Thus the inclusion of emulsifying agents within BUIKSTA et al.

does not anticipate such emulsifying agents as contributing to oxidative stability, nor contributing to enhanced stability during prolonged shelf life under room temperature conditions (i.e., non-heated). There is no suggestion that a highly modified polycationic CPP as claimed in the present invention may be used in addition to standard emulsifying agents.

Musher et al. U.S. Patent Number 2,282,815 is directed to stabilization of oils during the refining process, which has very high temperature requirements as compared to shelf-life stability. In such a composition, the enhanced antioxygenic effect is only obtained at processing temperatures in excess of 250 °F. The heating process is in fact required to achieve dispersion of the stabilizing agents noted as phosphatides, phosphoric acid and the salts of phosphoric acid and a nitrogen compound. There is no suggestion that the claimed polycationic CPP complex of the present invention may be used in addition to standard emulsifying agents. There is no suggestion that elimination of the heating process will enhance the antioxygenic effect, which by inference is required to disperse the stabilizing agents.

The Claims Patentably Distinguish Over the Art Cited of Record

None of the references of record suggest the use of polycationic casein phosphopeptides, or of polycationic casein phosphopeptides derived from the casein fraction of milk or any modification of such phosphopeptides as an antioxidant, or as a means to prevent hypercholesterolemia.

Antrim et al. U.S. Patent Number 4,963,385 fails to disclose any distinction between reducing and non-reducing sugars and sugar polyols. Furthermore, in the present invention chitosan (i.e., is not a metal chelator) assumes a polycationic character at acidic pH (pH 2.0-5.7). This polycationic chitosan molecule reacts with the high negative charge contributed by the phosphate groups of caprine casein phosphopeptide to form a "polycationic complex". This polycationic complex reacts with the phosphate groups of lecithin-emulsified oil droplets and sulfated groups of polysaccharides

(carrageenans, heparin, chondroitin, dextran, and cyclodextrins) to form a biopolymeric complex. This biopolymeric complex efficiently encapsulates and sequesters “natural” antioxidants such as the Vitamin E complex (tocotrienols, tocopherols) and pro-Vitamin A (beta-carotene). The polyphenols present in the eggplant fruit (*Solanum melongena*) can be used in combination with the biopolymeric complex to effectively inhibit peroxide formation in emulsified lipids.

Buikstra et al. U.S. Patent Number 5,650,190 fails to disclose or suggest any benefits from the emulsifying agents beyond recognized emulsification.

Musher et al. U.S. Patent Number 2,282,815 fails to provide an inherent method to disperse stabilizing agents without temperatures in excess of 250 °F. It further fails to disclose any distinction between reducing and non-reducing sugars and sugar polyol.

Han et al do not teach or suggest use of pH modifiers at all. Antrim et al do not teach or suggest using caseine phosphopeptide. Antrim et al disclose emulsions containing 60 to 80% by weight oil phase and 40 to 20% milk or aqueous phase (see Antrim et al., column 3, lines 15-44), thus indicating clearly milk can be substituted with water. The implied suggestion in this reference is that milk is not necessary for the invention to work as it works fine with just water. There is no suggestion whatsoever to favor milk instead of water. In addition, milk proteins are not the same as the casein phosphopeptide. To obtain phosphopeptides from casein one must engage in the enzymatic hydrolysis of casein or casein fraction proteins to derive casein phosphopeptide. Thus, a combination of Han et al and Antrim et al to arrive at the present invention is not obvious for a person of skill in the relevant art. Accordingly, the Applicant respectfully submits that the rejection of 95, 104, 106, 108, 114 and 117 under 35 USC §103(a) as being unpatentable over Han et al, optionally in view of Antrim et al for claim 114, which is dependent on claim 105, is inappropriate and requests withdrawal of the rejection.

In response to the rejection of claims 91-92, 96-97, 109-110 and 112 under 35 USC §103(a) as being unpatentable over Han et al, optionally in view of Buikstra et al. or

Musher et al, the Applicants respectfully submit that the cited references do not suggest or provide any motivation to modify or combine.

As explained above and admitted by the Examiner, Han et al. do not disclose or suggest a combination as in claim 88. Buikstra et al. disclose medium-chain triglycerides, lecithin hydrolyzate and a protein hydrolyzate in preparation of emulsions. However, there is no suggestion or teaching in Buikstra et al. to combine other elements as in claim 88. More specifically, Buikstra et al fail to suggest or teach pH modifiers or tocopherols. Accordingly, this rejection is inappropriate, and hence, the Applicant respectfully submits that the claims are allowable over Han et al in view of Buikstra et al.

Musher et al. disclose stabilizing mixtures of glyceride oils at higher temperature above 300 °F and for long periods (see Musher at page 1, column 1, line 40-48; column 2, lines 38-50; page 3, column 2, lines 48-57). Musher et al require a combination of organic nitrogen compounds and phosphatides and/or sugars (see column 1, lines 26-31). Contrary to the Examiner's assertion, Musher et al. does not teach stabilization of water and oil emulsions containing highly unsaturated oils. Instead, Musher et al teach stabilization of glycerides at high temperatures. Musher et al do not disclose tocopherols or pH modifiers. Further, Musher discloses that charring occurs during the process and it is desirable to heat to elevated temperatures to obtain fully desirable results of the invention (see Musher page 2, column 2, lines 1-6). Accordingly, Musher et al do not disclose or suggest the emulsion combination of the claimed invention. Accordingly, this rejection is inappropriate, and hence, the Applicant respectfully submits that the claims are allowable over Han et al in view of Musher et al.

In response to the rejection of claims 88-119, under 35 USC §103(a) as being unpatentable over Buikstra et al. or Antrim et al, in view of Han et al, the Applicants respectfully submit that the cited references do not suggest or provide any motivation to modify or combine.

The Examiner acknowledges that "there is not an explicit disclosure to the addition of applicant's claimed casein phosphopeptides to the food compositions/emulsions that these patents disclose." (See Office Action dated February 17, 2006, page 8, lines 1-4) However, the Examiner alleges that it would have been

obvious to use the disclosure of Han et al to advantageous incorporation of caseinophosphopeptides into food products. As explained above, Buikstra et al do not suggest or teach to combine other elements as in claim 88, especially Buikstra et al fail to suggest or teach pH modifiers and tocopherols.

Antrim et al disclose only emulsions containing 60 to 80% by weight oil phase and 40 to 20% milk or aqueous phase (see Antrim et al., column 3, lines 15-44), thus indicating clearly milk can be substituted with water. In addition, milk proteins are not the same as the caseinophosphopeptide. To obtain phosphopeptides from casein one must engage in the enzymatic hydrolysis of casein or casein fraction proteins to derive casein phosphopeptide. Accordingly, Antrim et al neither teach nor suggest a combination as in claim 88 to a person of ordinary skill in the art, and hence, this rejection is inappropriate.

Accordingly, the Applicant respectfully submits that all the claims are in condition for allowance.

Summary

Applicant restates and incorporates by reference all previous remarks made in prior Responses made of record in this case. Applicant's Amendment introduces new limitations on the casein phosphopeptide in the amended independent Claims 88, 105, and 118 which positively recited that the claimed antioxidant composition is comprised of a polycationic casein phosphopeptide complex.

Applicant submits that the pending claims are in proper condition for allowance. Moreover, Applicant submits that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited.

No additional fees are believed necessitated by the presentation of these amendments. The Director is authorized to deduct any additional expenses from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Appl. No. 10/784,842
Amdt. Dated 17-Feb-2006
Supplemental Preliminary Amendment
Attorney Docket No. : 6037-006

Should the Examiner find that there are any outstanding matters that are susceptible of resolution by telephone interview, the Examiner is invited to telephone the undersigned to discuss the same.

Respectfully submitted

A handwritten signature in black ink, appearing to read 'David G. Rosenbaum', with a long horizontal flourish extending to the right.

David G. Rosenbaum
Reg. No. 31,872

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